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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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			EXAMINER NASHED, NASHAAT T	
			ART UNIT	PAPER NUMBER

1656

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/998,284

Applicant(s)

POULSEN ET AL.

Examiner

Nashaat T. Nashed, Ph. D.

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,9-15 and 30-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,9-15 and 30-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/17/05 & 7/28/05</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1656

The application has been amended as requested in the communication filed November 17, 2005. Accordingly, claims 1 and 33 have been amended, claims 4, 6, and 7, and new claims 37 and 38 have been renumbered claims 38 and 39, respectively, and entered. The fate of claim 37 entered to the record in the amendment filed June 1, 2005 is not clear. It is presumed that claim 37 has been canceled. Clarification of the record is required.

Claims 1-3, 9-15, 30-36, 38, and 39 are under consideration.

The disclosure is objected to because of the following informalities: At pages 6 and 31, last line, and line 27, respectively, and claims 3, 32, and 37; the name of the genus is "*cripus*", whereas, at page 8, line 9, and page 21, line 13 it is written "*crispus*". The prior art of record indicates that it should be "*crispus*", see Hansen *et al.*

Appropriate correction is required.

Claims 3, and 32 objected to because of the minor objection to the specification stated above. Appropriate correction is required.

Applicants are not responsive to the above objection to the specification and the claims.

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-Reference to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc (see 37 CFR 1.52(e)(5)).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).

- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing, if on paper (see 37 CFR 1.821-1.825).

While the exact format of the application is not required as stated above, the various elements should be labeled and present in the specification. The application for example contains Figure 1, but it does not contain a figure description, which is required, see below for further details.

Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive; preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.
- (d) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

Or alternatively, Reference to a "Microfiche Appendix": See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.
- (e) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject

Art Unit: 1656

matter of the claimed invention. This item may also be titled "Technical Field."

- (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (f) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.
- (g) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (h) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (i) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation.

There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

- (j) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).
- (k) Sequence Listing. See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Applicants are not responsive to the above objection to the specification.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 9-15, 38 and 39 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "which is long-acting" in claim 1 and its dependent claims is considered a new matter and should be deleted from the claims because the limitation appears nowhere in the specification. Also, the phrase "long term effectiveness" at page 4 of the specification does not provide sufficient support for the phrase "long-acting" because the composition may be "long-acting" without being effective. Similarly, the phrases "at least four weeks" in claim 38 and "at least two years" in claim 39 are considered new matter because they do not appear anywhere in the specification. Applicants monitored the composition's anti-fouling ability for up to four weeks and two years in examples 4 and 6, respectively. They report the composition to be effective at preventing fouling at the end of these time periods, but it does not support acting beyond these time periods, which is

Art Unit: 1656

encompassed by the "at least" language of the claims. Applicants are required to remove all new matter from the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-3, and 9-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "long-acting" in claim 1 is a relative term, which renders the claim indefinite. The term "long-acting" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention. It is not clear how long is long acting. Claims 2-3 and 9-15 are included with this rejection because they are dependent from rejected claim 1 and do not cure its deficiencies.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 9-15, 30-36, 38, and 39 are rejected under 35 U.S.C. 103 as being unpatentable over Hamade *et al.* (IDS: reference AF, EP-0866103 A1) in view of Hansen *et al.* [J. Biol. Chem. 272 (17), April 25, 1997, pages 11581-11587] and James *et al.* [J. Food Biochem. 1997, 21, 1-52].

Claims 1-3, 9-15, 30-32, 34-36, 38, and 39 are rejected under 35 U.S.C. 103 as being unpatentable over Hamade *et al.* (IDS: reference AF, EP-0866103 A1) in view of U. S. Patent 6,251,626 B1 [626 patent, Stougaard *et al.*] and James *et al.* [J. Food Biochem. 1997, 21, 1-52].

Hamade *et al.* teach a method preventing fouling surfaces submerged in water by in which an anti-fouling agent is produced by an enzyme action on its substrate, and anti-fouling composition comprising an enzyme and its substrate, see abstract. They specifically teach an enzyme substrate combination capable of producing hydrogen peroxide and exemplify the enzyme-substrate combination with glucose oxidase-glucose and hexose oxidase-glucose, see page 5, lines 14-22. Also, they teach that the

substrate of the enzyme that produces the antifouling agent can be generated by the action of another enzyme or enzymes, see page 3, lines 38-46, as well as the control release of the antifouling agent produced by the action of the enzyme in a paint composition. Thus, Hamade et al. teach the claimed composition and method except that they did not teach the enzyme from a marine organism such as *Chondrus crispus*, in particular the hexose oxidase of SEQ ID NO: 2 found in claims 2, 3, and 31-33, or the use of carbohydrate or sugar as substrate for first enzyme, or the generation of glucose by the action of amyloglucosidase on starch in claims 9, 10, and 30-39.

The teaching of Hansen *et al.* and 6,251,626 references are summarized in the previous office action, mailed June 17, 2005.

James *et al.* is a review article on glucoamylases, microbial source and industrial applications. It teach that glucoamylase catalyzes the hydrolysis from the non-reducing chain ends by cleaving α -1,4 and α -1,6 glycosidic bonds consecutively and its use for the hydrolysis of starch for various purposes, see the abstract, and that gluciamylase has been loosely called amyloglucosidase, see the introduction at page 2, line 2. They teach that starch consists of two branched polysaccharides named amylose and amylopectin both of which are made of glucose, see starch structure starting at page 2. The various starch hydrolases action on starch and the product of hydrolyses of α -amylase, β -amylase and glucoamylases. Only, glucoamylase produces glucose whereas the others produce oligosaccharides and disaccharides, see page 4. Glucoamylase convert starch completely to glucose, see page 5, second paragraph. There are several known glucoamylases from various biological sources having suitable properties for industrial application, see page 9-16. James *et al.* teach that Glucoamylase is cheap and commercially available as a free enzyme or immobilized enzyme from several source, see page 22-25 and Table 2 in particular at page 23.

Hamade *et al.* teach an anti-fouling composition comprising hexose oxidase as well as a composition comprising an additional enzyme and substrate to generate glucose for hexose or glucose oxidase. Hansen et al. and '626 provide one of ordinary skill in the art at the time of invention with motivation to use the hexose oxidase from *C. crispus* as they teach that hexose oxidase is a superior substitute to glucose oxidase for all of its uses because of its broader substrate specificity. Thus, it would have been obvious at the time of invention to one of ordinary skill in the art to formulate and anti-fouling composition as taught by Hamade *et al.* comprising a precursor substrate, a first enzyme to hydrolyze the precursor substrate, and the hexose oxidase, taught by Hamade *et al.*, in particular, that from *C. crispus*, a marine organism, taught by Hansen *et al.* and the '626 patent, and use said composition to treat surfaces such as outdoor wood work and the hull of marine vessels (claim 1-3, and 12-15). Although Hamade *et al.* do not teach specifically the use of amyloglucosidase to act on the precursor substrate to produce the substrate for the hexose oxidase, they teach any enzyme/substrate combinations that lead to the formation of any substrate for the hexose oxidase would be a good combination, see page 3, lines 38-46. The teaching of

Art Unit: 1656

James *et al.* provides one of ordinary skill in the art with motivation to use amyloglucosidase as they teach the commercial availability of the enzyme from various sources having different properties and stability, the complete hydrolysis of starch to glucose, and the fact that the only product of the action amylocosidase is glucose, which is the desired substrate for hexose oxidase (claim 9, 10, and 30-36). Another useful property of amyloglucosidase, which would have further motivated the ordinary skill in the art, is its ability to act on purified and raw starch, see Table 1 at page 10. Since the action of amyloglucosidase on starch is well-known in the prior art to produce glucose, see for example the '900 patent, it would have been obvious to one of ordinary skill in the art at the time of invention to use amyloglucosidase to produce glucose from starch in the claimed composition (claims 1-3, 9-15, and 30-36). Finally, Hamade *et al.* teach that the antifouling composition is a controlled release composition because the lack of water in the matrix where all reaction takes place (claim 38 and 39). Thus, the claimed invention was within the ordinary skill in the art to make and use at the time was made and was as a whole, clearly *prima facie* obvious.

In response to similar rejection in the previous Office action, Applicants assert that the teaching of Hamade *et al.* is misunderstood and point out the hydrolysis of chitosan produces antifouling agent and not a substrate for the second enzyme. They further argue that the teaching of Hamade *et al.* does not teach two enzyme system to produce the antifouling agent, and one of ordinary skill in the art would come to the conclusion that the teaching of Hamade *et al.* reads to a situation, where a naturally occurring enzymatic or chemical reaction runs as a second reaction.

Applicants arguments filed 10/17/05 have been fully considered, but they are found unpersuasive. While the examiner reiterate his misreading Hamade *et al.*'s teachings at page 5, the teaching at page 3 is quite clear. Hamade *et al.* specifically stated:

It should be understood that said compound having antimicrobial activity may be a compound obtained as the direct result of enzymatic reaction between the enzyme and the substrate or a compound formed from the product of such enzymatic reaction through further enzymatic or chemical reaction.

The statement as presented that the antifouling compound can be produced directly by the direct action of an enzyme on its substrate or through a compound formed through further enzymatic reaction. The statement does not qualify the number of enzymatic reactions or the source of other enzymes, and clearly indicates a multienzyme composition is within Hamade *et al.* teachings. Thus, the teaching of more than one enzyme to produce the antifouling compound is clearly suggested. The instant claims are directed to a method in which a first substrate, in particular, a carbohydrate or sugar is converted by the action of a first enzyme to a second substrate, which is converted by hexose oxidase. It is undisputed fact that an antifouling composition comprising the hexose oxidase and one of its multiple known substrate is taught by Hamade *et al.*

Art Unit: 1656

Amyloglucosidase is a well known industrial enzymes used to convert starch to various products, and is commercially available in different form and properties, which would have provided motivation to the ordinary skill in the art to specifically use the combination of amyloglucosidase and starch in the composition. Thus, the claims are *prima facie* obvious over the cited prior art of record.

Applicants allege that a key feature for the practical application of the invention of Hamade *et al.* is that the substrate is insoluble, whereas the antimicrobial compound is soluble. The examiner disagrees with applicants' statement because Hamade *et al.* teach the production of hydrogen peroxide from the action of hexose oxidase on glucose. Both Glucose and hydrogen peroxide are water-soluble compounds. With regard to the control release argument, applicant should note starch is a water-soluble material. The presence of the starch in the claimed dry paint composition in a matrix prevents its dissolution into water. The present composition uses the same principal of incorporating a water-soluble compound to control its release. Thus, the claimed invention is clearly obvious over the teaching of Hamade *et al.*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTWTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen M. Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
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